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ARTICLE

A Randomized, Community-Based Trial of Home Visiting to Reduce Blood Lead Levels in Children

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ABSTRACT

OBJECTIVE. The objective of this study was to measure the effectiveness of intensive case management to reduce blood lead levels (BLLs) in children. Lead poisoning remains a common, preventable pediatric condition despite advances in reducing children's BLLs in the United States. Substantial evidence implicates lead paint–contaminated house dust as the most common high-dose source of lead in children's environments. Housekeeping and parental supervision also may contribute to risk for lead exposure.

METHODS. We conducted a community-based, randomized trial of comprehensive education and home visiting for families of children with BLLs 15 to 19 μg/dL. BLLs after 1 year of follow-up were compared for intervention group children, whose families received individualized education that was designed to address specific risks factors in a child's environment, and comparison group children, whose families received customary care, usually 1 or 2 educational visits. Environmental samples were collected at baseline and after 1 year of follow-up for intervention group children and compared with those of comparison group children, collected only at the end of study.

RESULTS. During the follow-up period, parents of intervention group children (n = 92) successfully decreased dust lead levels and significantly improved parent-child interaction and family housekeeping practices compared with comparison group children (n = 83). Overall geometric mean BLLs declined by 47%, and the difference in BLL by group was not significant (9 vs 8.3 μg/dL for intervention versus comparison group children, respectively.) After 1 year, nearly half of enrolled children had BLLs ≥10 μg/dL.

CONCLUSIONS. Until a reservoir of lead-safe housing is created, programs that educate families to reduce environmental exposure are needed. Although providing families with quantitative information regarding lead contamination may have a role in short-term efforts to prevent lead exposure, these null findings suggest that it has little benefit once BLLs are elevated.

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Key Words
lead poisoning, home visiting, case management

Abbreviations
BLL—blood lead level
NCATS—Nurse Child Assessment Satellite Teaching Scale
GM—geometric mean
CI—confidence interval

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THE SERIOUS CONSEQUENCES of lead exposure during childhood have been reviewed systematically since 1943, when Byers and Lord[1] first presented data on school failure for 20 children who had been hospitalized for lead ingestion in early infancy. In the 60 years after this publication, a compelling body of data that demonstrates that lead exposure in early childhood compromises children's later intellectual development and life achievement has been accumulated.[2–11] No blood lead level threshold below which children are safe from the adverse effects of lead exposure has been identified.[12,13]

Efforts to reduce blood lead levels (BLLs) in the United States have been a resounding public health success.[14] However, an unacceptable number of children are exposed to lead each year. Specific populations and regions experience disproportionately high levels of lead poisoning, particularly young, black, and central-city residents.[15–17]

Substantial evidence implicates lead paint–contaminated house dust, ingested during normal mouthing behaviors, as the major source of lead exposure for young children in the United States.[18–22] Interventions that are designed to reduce lead contamination in house dust and limit children's access to residential lead hazards usually are implemented after identification of a lead-poisoned child. The efficacy of these interventions remains an open question. Initial retrospective reports of parental education and empowerment were encouraging.[23] However, because these were uncontrolled trials with results that depended on retrospective or repeated measure designs, their scientific merit was limited. A number of studies have evaluated house cleaning and parental education interventions to control exposure to leaded house dust. In a randomized trial of the efficacy of regular home cleaning, investigators found that cleaning by professional cleaners, accompanied by maternal education, is safe and partially effective in reducing BLLs.[24] However, in 2 trials in which dust control was performed by families, 1 study concluded that education was not effective in preventing lead exposure, and the other found that although 19% of children who received an intensive education later had an elevated BLL versus 27% of control group children, education alone cannot prevent lead burden.[25,26] Dust cleanup as a 1-time, low-cost strategy in housing with existing lead paint hazards has proved disappointing as a primary prevention strategy.[27] Other factors that are thought to be associated with increased risk for lead poisoning among children include nutritional status, particularly for iron and calcium; the perception that the risk is minor; poor housekeeping and personal hygiene; and inadequate parent-child interaction.[28]

Here we present the findings of a randomized, community-based trial that was designed to measure the effectiveness of intensive case management to address the behavioral and environmental factors that are thought to affect lead exposure compared with standard case management. This study was approved by the Rhode Island Department of Health, Harvard School of Public Health, and the Centers for Disease Control and Prevention human subjects committees.

METHODS

All children who were identified through routine blood lead testing as having venous BLLs 15 to 19 μg/dL and reported to the Rhode Island Department of Health between July 1999 and June 2002 were referred to the study. Families of children who qualified for the study because (1) the child was <28 months of age, (2) the child had a venous BLL of 15 to 19 μg/dL, and (3) the family spoke English or Spanish were invited to participate. A random-numbers table was used to assign cases to either the intervention or the comparison group, sequentially by the study coordinator (M.J.B.). Group assignments were sealed into envelopes and unknown to either study personnel or the families until after parental consent was obtained.[29] The nurses who provided follow-up to comparison group children were blinded to whether any given child was a study participant. Nurses who provided care to intervention group children were not blinded as to the child's status.

Intervention Group

Children received a series of 5 home visits during the 1-year follow-up period. Nurses (1) collected interior dust and soil samples using a standardized protocol; (2) evaluated parent-child interaction using the Nurse Child Assessment Satellite Teaching Scale (NCATS), which measures the mother-infant pair sensitivity to cues and the clarity of the mother's communication; and (3) identified occupational or recreational exposure to lead sources and other factors that are thought to influence lead exposure or absorption using a standardized questionnaire first developed by the US Department of Housing and Urban Development and the Centers for Disease Control and Prevention.[30] A detailed and individualized nursing care plan directed parent teaching and other services. Families were given the results of all environmental and blood lead testing as soon as these were available.

Comparison Group

Children received customary care, in most cases, in 1 or 2 educational visits by an outreach worker. These visits focused on standard health education about lead poisoning and its prevention but did not include environmental sampling, education tailored to individual circumstances, or standardized assessment of nutrition or parent-child interaction. Data for comparison group children were collected at the end of the follow-up period, when nurses (1) collected interior dust and soil samples, (2) evaluated parent-child interaction, and (3) identified occupational or recreational exposure to lead sources using the tools listed above. Families were given the results of BLL tests and environmental sample results as soon as they were available.

Blood Lead Analysis

Venous blood samples were collected by children's pediatric health care providers and measured by graphite furnace atomic absorption spectroscopy that was conducted by 1 laboratory that had proficiency in blood lead testing and adhered to the Clinical Laboratory Improvement Amendments.

Environmental Lead Analysis

Dust wipes were digested using a method described by the United States Department of Housing and Urban Development.[31] Soil was dried, sieved to a particle size of <250 μm, homogenized, and digested using a modified National Institute for Occupational Safety and Health 7082 procedure. Dust wipe and soil digestates were analyzed by flame atomic absorption spectroscopy according to EPA SW846-7420 EPA 239.1. The Hematology and Environmental Laboratory of the University of Cincinnati performed all sample preparation and analysis. The laboratory is accredited by the National Industrial Hygiene Association as an Industrial Hygiene Laboratory and is recognized under the National Lead Laboratory Accreditation Program as an Environmental Lead Laboratory. Consequently, the laboratory participates in the Proficiency Analytical Testing Program and the Environmental Lead Proficiency Analytical Testing Program. The laboratory is certified through the State of New York as a National Environmental Laboratory Accreditation Conference laboratory and participates in the New York proficiency program for environmental sample analytes, including lead.

Data Analysis

Statistical analyses were performed using SAS version 8.02. Because BLLs and dust lead levels were not normally distributed, log transformation was used. BLLs and dust lead levels below the limit of detection were substituted by the limit of detection divided by $\sqrt{2}$ based on the log-normal distribution of BLLs and dust lead levels. Paired *t* tests were used to test for a change in mean or geometric mean (GM) within group blood or dust lead values from one sampling time to another. Wilcoxon signed rank test was used to test for a median change in intervention group children's blood and dust lead values from one sampling time to another. Two-sample *t* tests were used to test for equality of mean (eg, NCATS score) or GM values for intervention versus comparison group children's blood or dust lead values. Wilcoxon rank sum tests were used to test for equality of median values for 2 groups. McNemar's test was used to test for a change in percentage of children with elevated BLLs as well as for a change in the percentage of families with more frequent housekeeping from one sampling time to another. Analysis of variance was used to test for equality of mean or GM values for >2 groups. Cochran-Mantel-Haenszel row-mean-score statistic was used to test for equality of an ordinal response variable in 2 groups. Regression analysis was used to examine predictors of an outcome of interest. Nested models were used to examine predictors of blood or dust lead levels when multiple observations from the same child were included. Survival-type modeling was done using product-limit survival estimates, and a likelihood ratio test was used to test the between-group difference in time from baseline to BLL <10 μg/dL.

RESULTS

Of the 241 families with children who were eligible, 175 (73%) consented to participate, and these children were randomly assigned: 83 children to the comparison group and 92 to the intervention group. For the 66 children whose families refused participation, work and school responsibilities were the most frequently cited reasons for nonparticipation. Parents of 2 enrolled children refused the first and all subsequent visits; the families of 9 other children refused to participate at some time during the study, and 2 children were lost to follow-up. Another 9 children moved out of state and were dropped from the study. The odds of not completing the study did not differ significantly between comparison and intervention group children (odds ratio [OR]: 1.4; 95% confidence interval [CI]: 0.6–3.6). Intervention and comparison children also did not differ on factors that are known to affect risk for elevated BLLs (Table 1).

TABLE 1 Characteristics of Study Population

Variable	Intervention Group	Comparison Group	*P*
Child's age, mo (*n*)	19.1 (90)[a]	18.8 (83)[a]	.71
GM BLL, μg/dL (*n*)	16.5 (90)[a]	16.3 (83)[a]	.35
Average number of moves in study period (*n*)[b]	0.4 (90)	0.5 (83)	.44
Smoker in home, % (*n*)	58 (89)[a]	47 (72)[b]	.20
Race/ethnicity, %[a]			
Black	7.8	9.6	.79
White	46.7	38.6[b]	.29
Hispanic (*n*)	40.0 (90)	49.4 (83)	.22
Average year housing constructed (*n*)[c]	1916 (90)	1914 (80)	.79
Average tax valuation of building in which child resides (*n*)[c]	$97 586 (90)	$142 604 (80)	.10
Children living in rental property, % (*n*)	62 (90)[c]	59 (83)[c]	.64
Reported family income, %			
<$50 000	50[a]	55[b]	.60
≥$50 000	18	16	.74
Not reported (*n*)	31 (90)	29 (72)	
WIC participation, % (*n*)	64 (89)[a]	55 (71)[b]	

WIC indicates Special Supplemental Program for Women, Infants, and Children.
[a] Evaluated immediately after enrollment.
[b] Evaluated after 1 year of follow-up.
[c] Evaluated during enrollment.

Dust lead levels significantly decreased, and these decreases were maintained through the follow-up period for the intervention group children. The most significant decreases occurred during the first 3 months of case management. Although decreases were sustained across the 12-month follow-up period and the percentage reduction doubled from 3 to 12 months, few measurements showed statistically significant changes between 3 and 12 months of follow-up. We observed this pattern in homes of all intervention group children, regardless of whether the family moved during the study (data not shown).

Baseline dust lead levels for the intervention group children did not differ significantly from those of the comparison group children collected 1 year after enrollment except that for floors identified as in poor condition. For these floors, dust lead levels of intervention group children were higher than those of comparison group children. However, dust lead levels of the intervention group children, collected 1 year after children were identified, were significantly lower than dust levels of the comparison group children (Table 2).

Reported housekeeping practices at baseline for intervention group children did not differ significantly from those for comparison groups after 1 year of follow-up. After 1 year of participation, intervention group families were significantly more likely than at baseline to report cleaning window sills and wells in the kitchen, child's bedroom, and living room and more likely to vacuum the living room and child's bedroom floor. These differences reflected a change in the reported frequency of damp cleaning for sills (from monthly to every 2 weeks) and for wells (from less than monthly to nearly every 2 weeks). In addition, in the intervention group, the level of cleaning observed by the nurse improved significantly from baseline to the 1-year visit ($P = .03$).

Parent-child interaction scores did not differ significantly between intervention and comparison group families at the time it was first administered. Intervention group children showed significant improvements over time in NCATS scores. After 1 year of follow-up, NCATS scores for the intervention group were significantly higher than those for the comparison group. Adjusting for child's age when the test was administered did not affect these differences (Table 3).

Both baseline and 12-month BLLs were measured for 145 (83%) of the 175 children enrolled in the study. The GM BLL at enrollment was 16.5 μg/dL (range: 15–19 μg/dL). The greatest reduction in BLLs occurred within 3 months after baseline, when the GM level fell by 37% to 10.3 μg/dL (interquartile range: 9–14 μg/dL; $n = 125$). By the end of the 12-month follow-up period, the GM BLL of participant children was 8.7 μg/dL (interquartile range: 7–12 μg/dL; $n = 145$), a 47% reduction from the baseline mean BLL.

The GM BLL did not differ significantly between intervention and comparison group children at 3, 6, or 12 months after baseline. In addition, the number of children whose last available BLL was ≥10 μg/dL did not differ between the groups: 42 (51%) in the comparison group versus 46 (51%) in the intervention group children. The percentage of children with any BLL ≥20 μg/dL also did not differ between groups (9 [11%] vs 7 [8%], comparison versus intervention group, respectively). Finally, no difference existed between the 2 groups in the time from baseline level to BLL <10 μg/dL (Fig 1).

DISCUSSION

Mouthing and other normal behaviors for children who are younger than 2 years result in high risk for exposure to lead in house dust. However, resources often are not available to remove lead paint permanently from children's environments, and legitimate concern exists that inexpert removal of lead paint hazards will result in more widespread contamination.[32–35] As a result, there has been a protracted search for inexpensive, low-technology interventions that would reduce BLLs by reducing house dust lead levels and mitigating other factors that are thought to influence lead absorption, particu-

TABLE 2 **GM Dust Lead Loadings: Comparison and Intervention Group Homes**

Surface	GM (μg/ft²)		
	Comparison Group	Intervention Group	
		Baseline	1-y Visit
Child bedroom sill (*n*)	75.7 (59)[a]	93.6 (1)[b]	28.0 (60)
Other sill (*n*)	52.3 (39)[a]	102.8 (53)[b]	25.4 (41)
Play, child bedroom and other floor (*n*)	8.8 (72)[a]	13.9 (89)[b]	5.5 (81)
Entry floor (*n*)	11.8 (72)[a]	13.3 (89)[b]	7.3 (80)

[a] Comparison of dust lead loading between comparison group children 1 year after enrollment and intervention group children 1 year after enrollment; $P < .05$.

[b] Comparison of dust lead loadings between comparison group children 1 year after enrollment and intervention group children at baseline; $P > .10$.

TABLE 3 **Comparison of Mean NCATS Scores According to Group**

Teaching Scales	Comparison Group Baseline (*n* = 69)[a]		Intervention Group (*n* = 88)			
			Baseline[b]		1-y Visit[c]	
	Mean	Possible	Mean	Possible	Mean	Possible
Child subscale	18.8	23	18.9	23	20.2[d]	23
Caregiver subscale	40.3	50	40.5	50	44.7[d]	50
Caregiver/child subscale total	53.1	73	59.4	73	64.8[d]	73
Child contingency	8.8	12	8.8	12	9.8[d]	12
Caregiver contingency	16.3	20	16.5	20	18.2[d]	20
Caregiver/child contingency total	25.1	32	25.3	32	28.0[d]	32

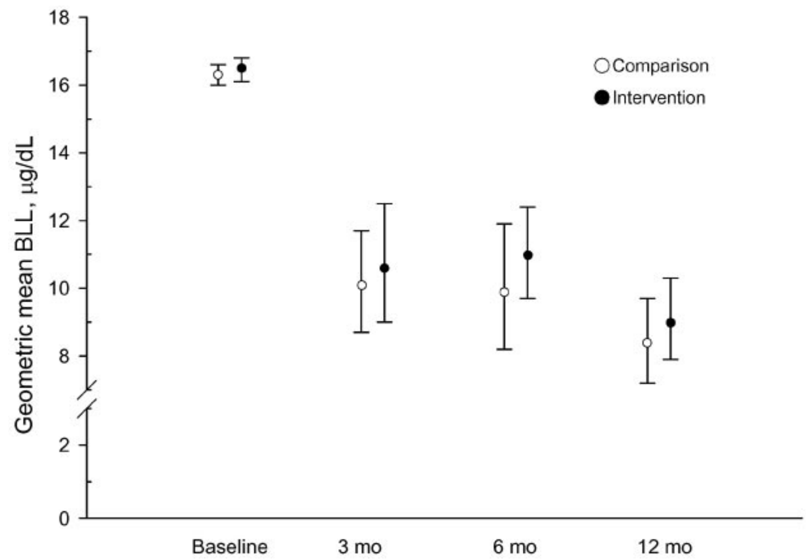
[a] Assessed 1 year after enrollment.

[b] Assessed at baseline.

[c] Assessed 1 year after enrollment.

[d] $P < .001$ compared to baseline scores for both comparison and treatment groups.

FIGURE 1
Comparison of GM BLLs: intervention group versus comparison group.



larly for children who have elevated BLLs and are not candidates for chelation therapy.

The few randomized trials of parent education and rigorous housekeeping to reduce BLLs once they are elevated have found either only modest improvements (a reduction of BLLs of 17% in the intervention group) or no difference in children's BLLs between children who received and did not receive the intervention.[24,25] Furthermore, concern exists that families could not on their own successfully reduce environmental lead contamination and maintain lower dust lead levels over time.[36] In 1 study of education to prevent lead burden in children, the likelihood of an elevated BLL was reduced by 34% in intervention compared with control group children, but the effect was of borderline significance.[26] In addition, although dust samples were collected in both intervention and control group homes, whether the decrease in risk for elevated BLLs is the result of changes in dust lead measurements over time was not reported.[26]

In this study, we found that within a primarily low-income, urban, minority population living in old, deteriorated housing, families who were informed of the dust lead levels and apprised of their success in lowering these levels over time were capable of the sustained effort that this required, whereas families who were educated about the dangers of lead dust but not given objective data about the extent of the contamination or feedback on their efforts to reduce it were not. We also found that families were willing to participate actively in efforts to reduce environmental lead levels; when families who moved out of state are excluded, fewer than 5% of families who were enrolled in this study dropped out before the end of their participation period.

The nurse case managers also helped families move toward a more supportive interaction and communication pattern with their children. This intriguing finding requires additional research for several reasons. First, higher NCATS parents' scores correlate significantly with subsequent measures of children's cognitive abilities, although the effect of improvements in the scores has not been examined over time.[37] Second, in experimental animal models, enrichment of the laboratory environment has increased brain mass across the animals' lifespan and, more recently, in rat models reversed the cognitive and molecular deficits that were induced by lead exposure during infancy.[38]

Until a reservoir of lead-safe housing is created, programs that educate families how to reduce dust lead levels are needed. However, although we demonstrated that a home visiting program that provides families with quantitative information regarding lead contamination can enable parents to reduce significantly dust lead levels, we could not demonstrate that this reduced BLLs of moderately poisoned children more than a less intensive strategy that did not result in decreased dust lead levels. In addition, after 1 year, nearly half of the enrolled children still had BLLs $\geq$10 μg/dL, the level targeted for elimination by the end of the decade.

It may be that the customary care provided to the children in the comparison group was sufficient to educate parents about the dangers of lead exposure and methods to reduce or limit children's access to residential hazards. However, given that dust lead levels at enrollment for intervention group children did not differ significantly compared with those of comparison group children collected at the end of the study, we have no evidence that the change in BLL was related to changes in the level of residential contamination. In addition, if customary care effectively reduced BLLs, then we would not expect nearly half of enrolled children to have BLLs $\geq$10 μg/dL a year after enrollment. It seems more likely that these findings are the result of developmental changes, primarily decreased hand-to-mouth behaviors as the children aged, coupled with bone lead mobilization as exposure to exogenous lead sources decreased, factors that presumably occurred equally in both groups. In a recent report of 3 lead-poisoned children, researchers estimated that up to 90% of lead in blood may be the result of mobilized skeletal lead depending on the child's age and exposure history.[39]

These findings also indicate that the benefits of programs that rely solely on interventions to reduce environmental lead contamination after children are exposed are limited. The nation should focus on developing and testing primary prevention strategies that protect children from becoming lead poisoned.

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